

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 100.0026PCT		Date of mailing (day/month/year) 06 MAY 2005
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US04/31886	International filing date (day/month/year) 29 September 2004 (29.09.2004)	Priority date (day/month/year) 30 September 2003 (30.09.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61F 2/06 and US Cl.: 623/1.12		
Applicant ALVEOLUS INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

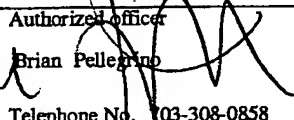
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Brian Pellegrino Telephone No. 703-308-0858
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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>8,10 and 11</u>	YES
	Claims <u>1-7 and 9</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-11</u>	NO
Industrial applicability (IA)	Claims <u>1-11</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-7,9 lack novelty under PCT Article 33(2) as being anticipated by Giantureo et al. '706. Giantureo discloses (Fig. 6) a stent with interconnected segments and have the support frame surrounded by a thread 40. Fig. 4 shows the stent is tubular and that deflection elements 20 are arranged on the circumference of the frame and on the end-side. Fig. 5 also shows the deflection has deflection elements 20' arranged on the inner side of the stent facing the middle and the adjacent annular segment 10" has a deflection element 20". Fig. 10B shows thread ends 56 coupled by connector 70. With respect to claim 9, it can be construed that additional guide elements are provided in the frame, see Fig. 3.

Claim 8 lacks an inventive step under PCT Article 33(3) as being obvious over Giantureo et al. Giantureo is explained above. Giantureo fails to disclose the connector tube is of a material that is x-ray visible. It is well known in the art to use radiopaque markers in delivery tubes. It would have been obvious to incorporate a marker in the connector tube of Giantureo to permit the surgeon to better see the end of the device as they remove the stent.

Claims 1-4,9 lack an inventive step under PCT Article 33(3) as being obvious over Bolea et al. in view of Giantureo et al. Bolea et al. disclose (Fig. 16) a tubular stent with segments interconnected and having two deflection elements 170 at the end-side. Fig. 19 shows the stent has a thread 80 guided from the outside into the support frame through the deflection elements. Fig. 18 shows the stent having additional guide elements. However, Bolea fails to disclose the thread ends are coupled by a connector. It should be noted that Bolea mentions the ends of the thread should be kept out of the lumen, paragraph 61. Giantureo teaches a tube or connector to hold the ends of the thread (Fig. 10A). It would have been obvious to one of ordinary skill in the art to use a connector or tube as taught by Giantureo with the stent apparatus of Bolea such that the ends of the thread can be kept out of the lumen of the vessel and prevent inadvertent blockage.

Claims 10,11 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Cox. Bolea as modified by Giantureo fail to disclose the annular segments are formed by struts and coupled with connector struts or a longitudinal section or spine running along the longitudinal axis. Cox shows (Figs. 2,9) a spine or longitudinal section along the axis. It can also be seen the strut section has a U-shape and is transverse with the spine since they extend across the spine. It would have been obvious to one of ordinary skill in the art to use a spine as taught by Cox in the stent of Bolea as modified by Giantureo such that it prevents foreshortening of the stent upon implantation.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The drawings are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or content thereof: the reference numbers are not plain and legible. Additionally black shading is not permitted because it prevents a clear illustration of the elements.

Claims 4-11 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: dependent claims which are drafted as multiple dependent cannot depend from other multiple dependent claims.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 4-6,9,11 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claim 4 is indefinite for the following reason(s): the claim recites "the end-side annular segment" which lacks antecedent basis. Claims 5,6 recite "the inner side" which lacks antecedent basis. Claim 6 also recites "the outer side of the annular segment" that lacks antecedent basis. Claim 9 recites "additional guide elements" that lacks antecedent basis. Claim 11 recites "each connector strut" which lacks antecedent basis.